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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,288	12/07/2000	Laurent Chevalet	PF83PCTSEQ/D	3732
25666	7590	05/05/2004	EXAMINER	
THE FIRM OF HUESCHEN AND SAGE 500 COLUMBIA PLAZA 350 EAST MICHIGAN AVENUE KALAMAZOO, MI 49007			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,288	<b>Applicant(s)</b> CHEVALET ET AL.	
	<b>Examiner</b> Konstantina Katcheves	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 17-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 1-21 are pending in the present application. The examiner thanks Applicant's representative, Dianne Newton, for faxing a copy of the active claims in the present application in order to confirm which claims are active in the present application.

#### ***Response to Amendment***

Claims 1-16 stand rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art at the time the invention was made that Applicant was in possession of the invention.

The rejection of claims 17-21 has been withdrawn in view of Applicant's amendment filed 7 April 2003 and upon reconsideration of the claims.

#### ***Response to Arguments***

Applicant's arguments filed 7 April 2003 have been fully considered but they are not persuasive. The claims cited above stand rejected for the reasons already of record and those set forth below.

Claims 1-16 stand rejected under 35 U.S.C. 112, first paragraph because the specification fails to describe the fragments of the genes encoding TnaA tryptophanase in such a way as to indicate that Applicant was in possession of the invention claimed. Applicant argues that "any person skilled in the art can generate a sequence of the gene encoding TnaA tryptophanase, or fragment thereof, and test the activity of the expressed mutated tryptophanase obtained in a cell

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using the "indole test" described on page 18, lines 6-13 of the Specification." In support of this position, Applicant has provided a declaration by Laurent Chevalet, PhD, describing mutant sequences which contain a missense stop codon, ICONE 100, which is also found in Example 1 of the Specification, or replacement of a TnaA gene coding fragment by a TrpR gene, ICONE 200, which is discussed in Example 2 of the specification.

With regard Applicant's argument regarding the indole test, the indole test described on page 18 of the specification teaches that mutants are cultured in tryptophan rich medium followed by the addition of Kovacs reagent. Trp mutants in the culture do not generate indole, from which it is deduced that the mutant have lost tryptophanase activity. As stated in the prior Office action rebutting this same argument:

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. See MPEP 2163(I)(A). Applicant has not specifically defined or described any structural characteristics commonly possessed by TnaA so that one of skill in the art would recognize that Applicant was in possession of TnaA sequences lacking tryptophanase activity. The indole test that Applicant relies upon as providing description of the broad genus of sequences lacking tryptophanase activity does not teach how the structure of a sequence relates to its function. Taking Applicant's argument to its logical conclusion, the claims read on any sequence, including sequences encoding other enzymes or any protein, so long as indole is not produced in a transformant. This is inarguably a broad genus for which ICONE 100 and ICONE 200 do not provide adequate written description.

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Moreover, the indole test allows one of skill in the art to "deduce" that the mutant does not have tryptophanase activity. The indole test does not provide for the very real possibility that tryptophanase activity occurs at such a basal level that the indole test cannot measure.

With regard to the declaration by Laurent Chevalet, the declaration refers to the generation of ICONE 100 and ICONE 200. See also Examples 1 and 2 of the specification. The disclosure of ICONE 100 and ICONE 200 as lacking tryptophanase activity is acknowledged. However, the disclosure of these two sequences does not provide adequate description for the broad genus claimed. As discussed above, the claims read on any sequence lacking tryptophanase activity, a very broad genus of sequences, for which ICONE 100 and ICONE 200 do not provide adequate written description. Thus, the declaration provided fails to provide sufficient information to overcome the present rejection under the written description requirement of the claims read on any sequence, 35 U.S.C. 112, first paragraph.

***Allowable Subject Matter***

Claims 17-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
22 April 2004



**JAMES KETTER  
PRIMARY EXAMINER**